

## REMARKS

Reconsideration in light of the following remarks is respectfully requested. Claims 1-23 are pending. An amendment to claim 1 has been proposed. Entry of the amendment is respectfully requested as it should put the case in condition for allowance or in better condition for appeal.

### Telephonic Interview

Applicants thank the Examiner A. Spiegler for the telephonic interview on October 27, 2003. The discussions of the references cited by the Examiner and the nature of the present invention were very helpful. This Office Action response incorporates those discussions and the proposed amendment herein also comes out of those discussions. The amendment therefore could not have been made earlier.

### Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement has been included with this response.

### Claim Amendments

Amendments to the claims have been proposed that should place the application in condition for allowance or present the claims in better form for consideration on appeal. Thus entry of the proposed amendment is respectfully requested. Step (b) has been amended to recite “assigning” rather than “determining”. Support for this amendment may be found throughout the specification. See, e.g., page 18, lines 11-13, “For each individual to be tested, prior probabilities are *assigned* for the probability of belonging to each of the candidate populations.” Furthermore, the term “assigned” is the term used in the art and therefore one of ordinary skill in the art would understand the meaning and scope of the term so it is definite. See, e.g., DeGroot et al. (representative pages submitted in the accompanying supplemental IDS), page 327, “we

defined prior probabilities of events to be the probabilities that were *assigned* to those events before the data of current interest were collected.”

Step (d) and step (e) have been amended to replace “determining” with “calculating” and “obtain” with “calculate”, respectively. Support for amending step (d) may be found in the specification. See, e.g., page 19, line 17 through page 21, line 15, where the specification provides one example of calculating a population genotype probability by a series of mathematical calculations. Support for step (e) may be found in the specification. See, e.g., page 21, line 18-30, where the specification provides an example of obtaining a population posterior genotype probability by combining the population prior genotype probability from step (b) and the population genotype probability from step (d) which is clearly a mathematical calculation and therefore provides support for “calculate”.

#### Claim Rejections – 35 U.S.C. § 103(a)

##### Gallo

###### A. The Examiner’s Rejection

Claims 1-11, 14-18, and 20-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gallo et al. (Genetica (1997) 110: 1-12).

###### B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires “assigning a *population prior genotype probability* for an individual ...” Step (e) requires “combining the *population prior genotype probability* from step (b) ...” Step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ...” Finally, step (g) requires “assigning the individual to the most likely population of origin ...”

### C. Cited Reference

The Examiner has stated that Gallo et al teach that you can determine the frequency of the suspect's profile against the relevant population databases. The Examiner has also stated that "Gallo does not teach the method steps as specifically outlined in the claimed invention..."

The Examiner has made further assertions about specific law enforcement practices. The Examiner has provided no support for these assertions. Applicants are unaware of the source of such assertions and therefore can not evaluate the relevance to the obviousness rejection. Applicants respectfully traverse this assertion and request that the Examiner provide references that discuss such law enforcement practices so that the applicants can better understand the Examiner's rejection. MPEP § 2144.03 "If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position."

### D. Reference Distinguished

35 USC 103(a) states "a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The *prima facie* case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success.

*No prima facie case:*

The Examiner fails to establish a *prima facie* case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention.

As amended, step (b) of claim 1 requires “assigning a population prior genotype probability for an individual and said each candidate population using knowledge concerning the individual which is available prior to genotyping the individual.” The Examiner has stated that the assignment of an individual to a pool of suspects is sufficient to meet this step (b). The Examiner indicated that this conclusion was reached by giving the claims their broadest reasonable scope. However, MPEP § 2111 clearly indicates that “The broadest reasonable interpretation of the claims must be consistent with the interpretation that those skilled in the art would reach.” Those skilled in the art are statisticians who would read the claim terms and understand that the term “population prior genotype probability” has a definite meaning in the art. The term “prior probability” is a term of art that refers to the numerical probability assigned before data of current interest is known, i.e., the numerical probability that an individual belongs to each of the candidate populations based on knowledge available prior to genotyping. See DeGroot et al., e.g. pg. 327 – “we defined prior probabilities of events to be the probabilities that were *assigned* to those events before the data of current interest were collected.” Furthermore, the specification clearly uses the term in the same way, i.e., as *numerical* probabilities. See, e.g., page 15, lines 12-14 of the specification. Thus, merely assigning an individual as a suspect does not meet the requirements of the claim element. To meet the requirements of this claim element, the law enforcement personnel would have to assign a numerical probability to an individual suspect, e.g., the suspect is 70% likely to be the perpetrator and 30% likely to be innocent, based upon data available before the genotype has been determined. Gallo et al do not teach assigning such numerical probabilities based upon information prior to genotyping. Thus, Gallo et al fail to determine a population prior genotype probability for an individual. Also, the Examiner has provided no evidence that law enforcement perform such a calculation, thus, both the cited reference and the example lack step (b) which is an element of the claimed invention.

As amended, step (d) of claim 1 requires “sequentially calculating a population genotype probability for the individual and said each candidate population based on the genotype of the

individual under a null hypothesis that the individual arose from said each candidate population.”

As defined in the specification, the population genotype probability is the numerical probability that an individual belongs to each candidate population. To calculate this, the law enforcement personnel would have to calculate the probability that a suspect is the perpetrator by comparing the alleles or markers in the suspects DNA to the allelic frequencies of the general population of non-suspects and to the alleles or markers found in the DNA at the crime scene to determine numerical probabilities of each, e.g., the law enforcement personnel would have to calculate the probability that the suspect was the perpetrator was 99.7% and the probability that the suspect was in the rest of the population was 0.3%. Again, this sort of calculation is just not performed in forensics. Law enforcement personnel merely look for a sufficient number of RFLP markers matching between the suspect’s DNA and the DNA found at the scene of the crime. The law enforcement personnel never compare the suspects allele’s to the bulk population. Furthermore, Gallo et al. do not perform this sort of calculation. Gallo et al. suggest instead comparing the genotype marker frequencies of the same ethnic group as the suspect with the DNA found at the crime scene to calculate the probability that someone else from the same ethnic group could have committed the crime. This is a different calculation and does not meet the requirements of step (d). Thus, neither Gallo nor the Examiner’s example teach or suggest this element of the claims.

As amended, step (e) of claim 1 requires “combining the population prior genotype probability from step (b) and the population genotype probability from step (d) to calculate a population posterior genotype probability for the individual and said each candidate population.”

Again, the interpretation of this step must be in light of one of ordinary skill in the art. As DeGroot et al teach, the term “posterior probability” distribution is a term of art with a definite meaning. See, e.g. page 72, indicating that  $\Pr(B_2|A)$  is a posterior probability and  $\Pr(B_2)$  is a prior probability as used in Example 2.3.7. Page 70 shows that  $\Pr(B_2|A)$  (the posterior probability) is calculated by combining  $\Pr(B_2)$  (the prior probability) with  $\Pr(A|B_2)$  (the new probability from the current data of interest. Furthermore, the specification supports this interpretation. See page 21, lines 18-30, for an example of such a calculation -  $\Phi_{ij}$  (the

population posterior genotype probability) is calculated by combining  $P_{ij}$  (the population prior genotype probability, page 18, line 32) with  $F_i(G_j)$  (the population genotype probability, page 21, lines 1-4). To meet this step, law enforcement personnel would have to combine the prior probability (e.g., the suspect is 70% likely to be the perpetrator and 30% likely to be innocent) with the population probability calculated in step (d) (e.g., the suspect is 99.7% likely to be the perpetrator and 0.3% likely to be innocent) to obtain a posterior probability (e.g., the suspect is 99.85% likely to be the perpetrator and 0.15% likely to be innocent). Neither the example provided by the Examiner nor Gallo et al teach or suggest such a combination of numerical probabilities to obtain a final numerical probability.

Finally, since neither the Examiner's discussion of law enforcement practice nor Gallo et al. include steps (b), (d) or (e), neither could teach step (f) because step (f) requires "identifying the most likely population of origin, wherein the most likely population of origin has the largest **population posterior genotype probability** ..." Since neither teaches generating a population posterior genotype probability.

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the references fail to teach steps (b), (d), (e), and (f).

Second, the Examiner has identified no motivation or suggestion in either discussing law enforcement practice or in Gallo et al to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, "The prior art must suggest the **desirability** of the claimed invention." The Examiner has merely stated that, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime." The Examiner, however, has not cited to any motivation or suggestion in Gallo et al. that it would be desirable to add the missing claimed steps **in particular**. Even if Gallo et al indicated that it would generally be

desirable to achieve the benefit of a higher predictability, nothing in Gallo suggests that the claimed elements not found in Gallo would be desirable. Neither Gallo et al. nor the Examiner's discussion of law enforcement practice mention or even suggest the missing claimed steps. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

Thus, even if Gallo et al and the Examiner's discussion of law enforcement practice supplied all claim elements, there is no motivation to combine them nor is there motivation to modify either to achieve the claimed invention.

#### Triggs

##### A. The Examiner's Rejection

Claims 1-11, 14-18, and 20-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Triggs (Science and Justice (2000) 40(1): 33-38).

##### B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires "assigning a *population prior genotype probability* for an individual ..." Step (e) requires "combining the *population prior genotype probability* from step (b) ..." Step (f) requires "identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ..." Finally, step (g) requires "assigning the individual to the most likely population of origin ..."

##### C. Cited Reference

The Examiner has stated that Triggs teaches "methods for assigning individuals from a population in mixed race populations, and more specifically outlines several different case

scenarios for assignment based on the steps outlined above.” The Examiner has also stated that “Triggs does not teach the method steps as specifically outlined in the claimed invention...”

D. Reference Distinguished

*No prima facie case:*

The Examiner fails to establish a prima facie case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention.

As amended, step (b) of claim 1 requires “assigning a population prior genotype probability for an individual and said each candidate population using knowledge concerning the individual which is available prior to genotyping the individual.” The Examiner has stated that the assignment of an individual to a pool of suspects is sufficient to meet this step (b). The Examiner indicated that this conclusion was reached by giving the claims their broadest reasonable scope. However, as discussed above, the term “prior probability” is a term of art that refers to the numerical probability that an individual belongs to each of the candidate populations. Thus, merely assigning an individual as a suspect does not meet the requirements of the claim element. To meet the requirements of this claim element, the law enforcement personnel would have to assign a numerical probability to an individual suspect, e.g., the suspect is 70% likely to be the perpetrator and 30% likely to be innocent, based upon data available before the genotype has been determined. Triggs does not teach assigning such numerical probabilities based upon information prior to genotyping. Thus, Triggs fails to determine a population prior genotype probability for an individual. Also, the Examiner has provided no evidence that law enforcement perform such a calculation, thus, both the cited reference and the example lack step (b) which is an element of the claimed invention.

As amended, step (d) of claim 1 requires “sequentially calculating a population genotype probability for the individual and said each candidate population based on the genotype of the



individual under a null hypothesis that the individual arose from said each candidate population.”

As defined in the specification, the population genotype probability is the numerical probability that an individual belongs to each candidate population. To calculate this, the law enforcement personnel would have to calculate the probability that a suspect is the perpetrator by comparing the alleles or markers in the suspects DNA to the allelic frequencies of the general population of non-suspects and to the alleles or markers found in the DNA at the crime scene to determine numerical probabilities of each, e.g., the law enforcement personnel would have to calculate the probability that the suspect was the perpetrator was 99.7% and the probability that the suspect was in the rest of the population was 0.3%. Again, this sort of calculation is just not performed in forensics. Law enforcement personnel merely look for a sufficient number of RFLP markers matching between the suspect’s DNA and the DNA found at the scene of the crime. The law enforcement personnel never compare the suspects allele’s to the bulk population. Furthermore, Triggs does not perform this sort of calculation. Triggs answers the question “If the suspect is not guilty what is the probability of obtaining this evidence [the DNA found at the scene of the crime as it matches or fails to match the suspect’s DNA]” See Page 38, col. 1. This is a different calculation and does not meet the requirements of step (d). Thus, neither Triggs nor the Examiner’s example teach or suggest this element of the claims.

As amended, step (e) of claim 1 require “combining the population prior genotype probability from step (b) and the population genotype probability from step (d) to calculate a population posterior genotype probability for the individual and said each candidate population.”

Again, the interpretation of this step must be in light of one of ordinary skill in the art. As discussed above, the term “posterior probability” distribution is a term of art with a definite meaning. To meet this step, law enforcement personnel would have to combine the prior probability (e.g., the suspect is 70% likely to be the perpetrator and 30% likely to be innocent) with the population probability calculated in step (d) (e.g., the suspect is 99.7% likely to be the perpetrator and 0.3% likely to be innocent) to obtain a posterior probability (e.g., the suspect is 99.85% likely to be the perpetrator and 0.15% likely to be innocent). Neither the example

provided by the Examiner nor Triggs teach or suggest such a combination of numerical probabilities to obtain a final numerical probability.

Finally, since neither the Examiner's discussion of law enforcement practice nor Triggs include steps (b), (d) or (e), neither could teach step (f) because step (f) requires "identifying the most likely population of origin, wherein the most likely population of origin has the largest ***population posterior genotype probability ...***" Since neither teaches generating a population posterior genotype probability.

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the references fail to teach steps (b), (e), and (f).

Second, the Examiner has identified no motivation or suggestion in either discussing law enforcement practice or in Triggs to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, "The prior art must suggest the ***desirability*** of the claimed invention." The Examiner has merely stated that, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime." The Examiner, however, has not cited to any motivation or suggestion in Triggs that it would be desirable to add the missing claimed steps ***in particular***. Even if Triggs indicated that it would generally be desirable to achieve the benefit of a higher predictability, nothing in Triggs suggests that the claimed elements not found in Triggs would be desirable. Neither Triggs nor the Examiner's discussion of law enforcement practice mention or even suggest the missing claimed steps. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

Thus, even if Triggs and the Examiner's discussion of law enforcement practice supplied all claim elements, there is no motivation to combine them nor is there motivation to modify either to achieve the claimed invention.

Ron

A. The Examiner's Rejection

Claims 1-12, 14-20 and 22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ron et al (J of Dairy Science (1996) 79(4): 676-681).

B. The Claimed Invention

Claim 1 is directed to a method of assigning an individual to a population of origin. The claim includes steps (a)-(g). Notably, step (b) requires "assigning a *population prior genotype probability* for an individual ..." Step (e) requires "combining the *population prior genotype probability* from step (b) ..." Step (f) requires "identifying the most likely population of origin, wherein the most likely population of origin has the largest *population posterior genotype probability* ..." Finally, step (g) requires "assigning the individual to the most likely population of origin ..."

C. Cited Reference

The Examiner has stated that Ron et al teach the DNA analysis of one hundred seventy-three cows, the progeny of four sires, which were sampled from 14 herds. The Examiner has asserted that this encompasses claimed steps (a) and (b). However, a review of the page 677 cited by the Examiner reveals no mention of determination of a population prior genotype probability for an individual and each said candidate population using knowledge concerning the individual which is available *prior* to genotyping the individual. The Examiner has further stated that the probabilities from step (b) and (d) were combined to determine the most likely population of origin of the cows. A review of pages 678 and 679 cited by the Examiner reveals

no mention of combining a population prior genotype probability with a population genotype probability to obtain a population posterior genotype probability. The Examiner also further stated that “Ron does not teach the method steps as specifically outlined in the claimed invention...”

D. Reference Distinguished

*No prima facie case:*

The Examiner fails to establish a prima facie case for obviousness. Specifically, 1) none of the cited references teach or suggest all of the claim limitations and 2) the prior art combined with general knowledge fails to include a suggestion or incentive to modify the references.

First, the reference fails to teach all limitations of the claimed invention.

As amended, step (b) of claim 1 requires “assigning a population prior genotype probability for an individual and said each candidate population using knowledge concerning the individual which is available prior to genotyping the individual.” The Examiner indicates that assignment of a herd of cows for a study satisfies the requirements of step (b). As discussed above, the term population prior genotype probability is a term with a definite meaning in the art. The Examiner has not pointed to any part of Ron et al. that includes assigning a numerical probability to the likely parent of an individual cow without reference to the genotype information, thus, the cited reference lacks this element of the claims.

As amended, step (d) of claim 1 requires “sequentially calculating a population genotype probability for the individual and said each candidate population based on the genotype of the individual under a null hypothesis that the individual arose from said each candidate population.”

As defined in the specification, the population genotype probability is the numerical probability that an individual belongs to each candidate population. Ron et al. do not teach the calculation of a probability that an individual belongs to a candidate population. Ron et al. calculate the probability that any given cow could be excluded from a sire. In actually deciding whether a cow is or is not the progeny of a given sire, no probability is calculated. Instead, a cow is

excluded because it lacks a genetic marker from the sire. See page 678, Figure 1 legend, “The fifth cow displayed neither paternal allele of CYP21 and is therefore marked with a slash.” Clearly, no numerical probability that the individual cow belongs to a given population of origin based on its genotype information is calculated.

As amended, step (e) of claim 1 requires “combining the population prior genotype probability from step (b) and the population genotype probability from step (d) to calculate a population posterior genotype probability for the individual and said each candidate population.” Since Ron et al. fail to teach assignment of a prior genotype probability from step (b) and a population genotype probability from step (d), Ron et al. cannot teach the combination of such as required in step (e).

Finally, since neither the Examiner’s discussion of law enforcement practice nor Ron et al. include steps (b), (d) or (e), neither could teach step (f) because step (f) requires “identifying the most likely population of origin, wherein the most likely population of origin has the largest ***population posterior genotype probability*** ...” Since neither teaches generating a population posterior genotype probability.

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the references fail to teach steps (b), (d), (e), and (f).

Thus, the Examiner has not established a *prima facie* case, because the references cited fail to teach all claim limitations. Specifically, the reference fails to teach steps (b), (d), (e), (f), and (g).

Second, the Examiner has identified no motivation or suggestion in Ron et al to make any modifications or combine other references. The MPEP is clear that a suggestion or motivation is not just any comment that modification of a reference or combination of references can be done. See MPEP 2143.01, “The prior art must suggest the ***desirability*** of the claimed invention.” The Examiner has merely stated that, “it would have been obvious to one of ordinary skill in the art at the time the invention was made to have carried out the claimed methods in order to have

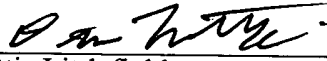
achieved the benefit of a higher predictability of positively identifying the perpetrator of a crime.” The Examiner, however, has not cited to any motivation or suggestion that it would be desirable to add the missing claimed steps. Ron et al do not mention the missing claimed steps or suggest adding them. Nor does a general desire to achieve the benefit of a higher predictability supply the necessary motivation. A general desire such as this does not lead specifically to the claimed invention. It merely motivates one of skill in the art to explore all the myriad possible ways to improve the accuracy of positively identifying the perpetrators of crimes.

Thus, the three obviousness rejections fail to establish a *prima facie* case because there are elements of the claims that are not found in the rejections. In addition, the nebulous motivation to combine or modify because it does not suggest the claimed invention, but rather suggests trying one of a large and undefined number of changes that could improve accuracy. Therefore applicants respectfully request that the Examiner withdraw the three obviousness rejections.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 529642000800.

Respectfully submitted,

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